REMARKS

1. Claim Rejection -- 35 U.S.C. § 102

Claims 1-6, 11-16 and 20-22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,963,360 to Argaud (hereinafter referred to as "Argaud"). Applicant respectfully traverses this ground of rejection.

An invention is unpatentable under 35 U.S.C. § 102(b) if "the invention was patented or described in a printed publication . . . more than one year prior to the date of application for patent in the United States." A 35 U.S.C. § 102(b) rejection is only appropriate, however, where "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See *M.P.E.P.* § 2131; *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). In addition, the identical invention must be shown in as complete detail as is contained in the ... claim." See *M.P.E.P.* § 2131; *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). For the reasons set forth below, Applicant submits that the reference cited by the Office neither teaches each and every element of the claimed invention, nor shows the identical invention in as complete detail as in Applicant's claims, and thus does not anticipate the present invention.

Argaud teaches an exothermic layer which develops heat when exposed to the air. See *Argaud, Abstract, Claims 1, 3.* In contrast, the present invention claims "a method of controlled delivery of analgesic" that includes a "temperature modification apparatus designed to deliver a particular dose of a drug at a pre-determined temperature range for a pre-determined duration of time, to deliver an appropriate amount of the drug." See *Claim 1.* In addition, the present invention claims "a temperature control apparatus

secured to said patch, said temperature control apparatus being capable of heating said patch and said patient's skin proximate said patch to a pre-determined range for a predetermined duration of time." See *Claim 22.* The Office has not shown these limitations in Argaud.

The present invention is specifically engineered to provide a certain amount of heat to the analgesic. In order to accomplish this level of control over the delivery of the analgesic, the temperature modification apparatus has been designed a particular way based on the many experiments explained in the specification. See *Examples 1-28 in the Specification, pages 21-64.* Exercising accurate control over the drug delivery process is important because the appropriate amount of drug is essential to the safety and health of the patient.

In contrast to the control aspect in the claims of the present invention, Argaud teaches an uncontrolled heating source with no mechanism for limiting the duration of time to a predetermined safe duration or for strictly limiting the amount of heat that is generated in the exothermic reaction. It is for this reason that the drugs cited in Argaud are not potent and are not considered particularly dangerous. This is because of the risk of overdose when using an uncontrolled heat source to increase the absorption of drug through the skin. When used with more potent drugs, such as those drugs used in the present invention (see *Specification, p. 37, lines 23-29 and p. 38, lines 1-5)* it would only be safe to use heat if the amount of heat and the duration of heat can be strictly controlled. That control is recited in the present claims.

The importance of the strict control of the heating can be illustrated by a tragic real life incident in which a young man wearing a transdermal fentanyl (a potent opiate

drug) patch prescribed to him for controlling an oral surgery pain slept in a heated water bed, and was found dead the next morning due to fentanyl overdose caused by the heat on the fentanyl patch.

In contrast to overdosing dangers, delivering the "appropriate amount" of a drug is also important because if not enough heat is provided, the drug is not effective.

Argaud does not teach preparing and deciding beforehand what the appropriate dosage should be. In contrast to the present invention, the concept of "control" is absent from Argaud's teachings.

The "method of controlled delivery" of claim 1 and the "temperature control apparatus" of claim 22 result in a closed system, whereas Argaud is an open system. In the closed system of the present invention, the amount of oxygen that enters the system is controlled, whereas in the open system of Argaud, oxygen enters uncontrolled into the system. Also, since the amount of heat generated is determined by the amount of surface area exposed to oxygen, the amount of heat generated can be varied by embodiments of the present invention as the amount of surface area exposed to oxygen is varied. Thus, by varying the amount of surface area exposed to oxygen, the amount of heat generated is controlled. In contrast to the controlled exposure to oxygen in the present invention, Argaud teaches the uncontrolled exposure to oxygen as oxygen freely enters through the air-permeable film. See *Argaud, Claims 1 and 3.* Consequently, Argaud neither actively controls the surface area's exposure to oxygen, the exothermic medium's shape, nor the amount of heat generated.

The ability of the present invention to control the time and rate at which the system and method generates heat allows for the improved administration of analgesics.

As disclosed in the many examples of Applicant's specification, the temperature modification apparatus is capable of administering analgesics over both a long period of time, such as the 240 minutes disclosed in Example 1, and over a short period of time, such as the 15 minutes disclosed in Example 3. See *Specification, page 32, lines 1-3.* In addition, the temperature modification apparatus is capable of keeping the skin temperature within various selected ranges. See *Specification, page 22, lines 25-26; page 34, lines 18-20.* The ability to control the temperature rage and duration of time improves the administration of analgesics by more effectively treating a variety of pains, illnesses, injuries and addictions, including localized pain, nicotine addiction, athletic injuries, cancer pain, inflammations, hypertension, depression, diabetes, migraines, asthma, obesity, and nausea. This ability to control is particularly helpful in customizing treatments, especially because different people react differently to the same drugs.

Consequently, because the Office has neither shown that Argaud teaches each and every element of the present invention, nor that Argaud shows the identical invention in as complete detail as presented in Applicant's claims, Argaud does not anticipate the present invention. Applicant respectfully submits that claims 1-6, 11-16 and 20-22 stand in a condition for allowance. As such, Applicant respectfully requests that the rejection under 35 U.S.C. § 102 be withdrawn.

2. Claim Rejection -- 35 U.S.C. § 103

Claims 1, 19 and 23 stand rejected under Section 103 as being unpatentable over Argaud. An invention is unpatentable under Section 103 "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which the subject matter pertains." To establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

In addition, under Section 103, the scope and content of the prior art are to be determined; the differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. MPEP § 2141.

A comparison of Argaud and the present invention shows important differences. As discussed above, the "method of controlled delivery" claim 1 and the "temperature control apparatus" of claim 22 result in a closed system, whereas Argaud is an open system. In the closed system of the present invention, the amount of oxygen that enters the system is actively controlled, whereas in the open system of Argaud, the entry of oxygen enters uncontrolled into the system. Also, since the amount of heat generated is determined by the amount of surface area exposed to oxygen, the amount of heat generated can be varied by embodiments of the present invention as the amount of surface area exposed to oxygen is varied. Thus, by varying the amount of surface area exposed to oxygen, the amount of heat generated is controlled. In contrast to the controlled exposure to oxygen in the present invention, Argaud teaches the uncontrolled exposure to oxygen as oxygen freely enters through the air-permeable film. See *Argaud, Claims 1 and 3.* Consequently, Argaud neither actively controls the surface area's exposure to oxygen, the exothermic medium's shape, nor the amount of heat generated.

One skilled in the art would not have been motivated to control the delivery of the medicinal component because no control mechanism existed to modify the exposure to oxygen. Argaud could only put in less exothermic medium, however the amount is not disclosed nor is there any discussion regarding varying the amount of medium.

In contrast to the claims of the present invention, Argaud teaches an uncontrolled heating source with no mechanism for limiting the duration of time to a predetermined safe duration or for strictly limiting the amount of heat that is generated in the exothermic reaction. When used with more potent drugs, such as those drugs used in the present invention (see *Specification, p. 37, lines 23-29 and p. 38, lines 1-5)* it would only be safe to use heat if the amount of heat and the duration of heat can be strictly controlled. Such control is recited in the present claims.

Applicant respectfully submits that claim 23, which claims the "step of applying a temperature modification apparatus proximate to said delivery site on said skin" that is "performed when said patient starts to feel the onset of breakthrough pain," is not obvious because of the control and speed required for effective treatment after the onset of breakthrough pain. This is evident in one disclosed embodiment of the present invention where a non-air permeable top wall with holes is used to control the rate of drug delivery. See *Specification, page 20, lines 20-21.* One way the present invention functions to increase the rate at which the drug is delivered is to uncover additional holes, exposing the exothermic layer to more oxygen, which in turn raises the temperature and increases the rate at which the drug is delivered.

In conclusion, the differences between Argaud and the present invention are substantial. Applicant respectfully submits that Argaud does not teach or suggest the

limitations discussed above. In particular, one skilled in the art of analgesic administration would not think to introduce the control of the present invention.

Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1, 19 and 23 under Section 103 as being unpatentable over Argaud.

CONCLUSION

Based on the foregoing, Applicant respectfully submits that the deficiencies in the application have been corrected and that the proposed claims are neither anticipated nor rendered obvious by the prior art references cited by the Examiner. As such, Applicant believes that the claims are now in a condition for allowance, and action to that end is respectfully requested.

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,

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